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IN THE

Supreme Court of the United States

OCTOBER TERM, 1994

BARR LABORATORIES, INC.,
Petitioner,

v.

BURROUGHS WELLCOME CO.,
Respondents.

Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether, for purposes of 35 U.S.C. § 101, one can be the inventor of a patentable pharmaceutical method of treatment (in this instance, the use of AZT to treat AIDS) when one has no reason to believe that such method will work.

PARTIES TO THE PROCEEDING

The parties to the proceeding below were the petitioner, Barr Laboratories, Inc., the respondent, Burroughs Wellcome Co., and two other pharmaceutical manufacturing companies, Novopharm, Inc., and Novopharm Ltd. Like Barr, Novopharm, Inc. and Novopharm Ltd. were defendants in the district court and appellants in the court of appeals.

The parties before this Court are the same as those below. Barr does not know whether a petition for a writ of certiorari will be filed by Novopharm, Inc. or Novopharm Ltd.

CERTIFICATION UNDER RULE 29.1

Barr Laboratories, Inc. has no parent company. Barr has two subsidiaries, BRL Incorporated and 265 Livingston Street Corp.

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PETITION FOR WRIT OF CERTIORARI

Barr Laboratories, Inc. hereby prays that this Court grant a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals is reported at 40 F.3d 1223 and is reproduced in the appendix hereto. App. A, 1a. The relevant opinion of the district court is reported at 828 F. Supp. 1208 and also is reproduced in the appendix hereto. App. B, 24a.

JURISDICTION

The court of appeals denied a timely petition for rehearing on December 15, 1994. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTES INVOLVED

35 U.S.C. § 101. Inventions patentable

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. § 116. Inventors

> When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.
>
> * * *
>
> Whenever through error a person is named in an application for patent as the inventor, or through error an inventor is not named in an application, and such error arose without any deceptive intention on his part, the Commissioner may permit the application to be amended accordingly, under such terms as he prescribes.

35 U.S.C. § 256. Correction of named inventor

> Whenever through error a person is named in an issued patent as the inventor, or through error an inventor is not named in an issued patent and such error arose without any deceptive intention on his part, the Commissioner may, on application of all the parties and assignees, with proof of the facts and such other requirements as may be imposed, issue a certificate correcting such error.
>
> The error of omitting inventors or naming persons who are not inventors shall not invalidate the patent

in which such error occurred if it can be corrected as provided in this section. The court before which such matter is called in question may order correction of the patent on notice and hearing of all parties concerned and the Commissioner shall issue a certificate accordingly.

STATEMENT OF THE CASE

The human immunodeficiency virus (HIV), a retrovirus, causes acquired immune deficiency syndrome (AIDS). HIV and AIDS are to the modern world a plague as devastating as those visited upon the pharaoh of the Exodus. The first licensed drug demonstrated to be active against HIV is 3'-azido-3'-azidothymidine, commonly known as AZT.

The principal issue in this case is whether six patents (the AZT Patents) relating to the use of AZT in the treatment of those infected with HIV[1] should be corrected by adding the names of scientists employed by the National Institutes of Health (NIH) as joint inventors (sometimes referred to as "coinventors"). The jurisdiction of the court of appeals was invoked under 28 U.S.C. § 1295(a)(1) and that of the district court under 28 U.S.C. § 1338.

The respondent, Burroughs Wellcome Co. (BW), is the owner of the AZT Patents as assignee of the five BW employees named as inventors on the patents (the BW Inventors). App. A, 2a. The petitioner, Barr Laboratories, Inc. (Barr), is the licensee of the rights of NIH in the AZT Patents. App. B, 27a. NIH is a component of the U.S. Department of Health and Human Services.

If NIH has rights in the AZT Patents, then Barr can manufacture and sell a generic version of AZT in the

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[1] HIV also has been referred to as HTLV-III, LAV, and the AIDS virus.

United States. If not, then BW will remain the sole source of AZT in this country until the AZT Patents expire in 2005.

In the early 1980s, scientists like Dr. Samuel Broder of NIH began to see patients who exhibited symptoms of a disease, now known as AIDS, that attacked the patients' immune systems in a way never before seen. App. A, 3a. AIDS attacks and destroys white blood cells called CD4 T-lymphocytes, or T-cells, that constitute an important component of the human immune system. App. A, 3a. Not until mid-1984 did scientists conclude that the cause of AIDS is HIV. App. A, 3a. At about the same time, HIV first was isolated in the laboratory, enabling experimentation with the live retrovirus and meaningful searches for potential drug therapies. Experimentation with live HIV is dangerous and requires special laboratory facilities to minimize the risk of infection.

Dr. Broder, assisted by Dr. Hiroaki Mitsuya of NIH, stepped up his previous efforts to identify an effective AIDS therapy. After several attempts, Broder and Mitsuya created a unique line of cells, called the ATH8 cell line, that could be used to demonstrate a chemical compound's effectiveness against HIV in humans.[2] App. A, 4a. Broder and Mitsuya began seeking compounds from private drug manufacturers for complex technical testing using the ATH8 cell line. App. A, 4a.

BW, a private drug manufacturer, began its own search for an AIDS treatment in June 1984. App. A, 3a. BW was unable to work with live HIV and therefore sought collaborations with outside researchers who were able and willing to work with the live virus. BW first contacted researchers at Duke University, one of whom introduced Dr. Broder of NIH to the BW team. BW in-

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[2] Broder and Mitsuya received a patent on the ATH8 cell line in 1987.

vited Broder to conduct a seminar at BW in early October 1984. On that occasion Broder and one of the BW Investors agreed that Broder would accept "candidate" compounds from BW for testing against live HIV.

Unlike Broder and Mitsuya, BW did not work with live HIV but instead screened compounds against two *mouse* retroviruses that did not present a risk of infection to humans. App. A, 3a-4a. Barr offered to prove at trial that the activity of a compound against the mouse screens is not predictive of the compound's activity against a *human* retrovirus such as HIV, that as a result BW used the mouse screens merely to generate a pool of candidate compounds, and that the mouse tests did not give—and could not have given—the BW Inventors a reasonable belief that AZT would work against HIV. App. B, 31a. As is discussed more fully below, Barr's evidence was excluded as irrelevant after the district court ruled that one can conceive an invention without any belief that the item or process will work in practice (or even if one believes that the item or process will *not* work in practice).

By early November 1984 the BW Inventors had tested 113 compounds, screened from its considerable inventory of substances shown to be nontoxic in mass toxicology and pharmacology testing. BW decided to submit eighteen of these to outside scientists. In mid-November 1984 one of the BW Inventors observed that AZT was active against the mouse retrovirus. BW thereupon added AZT to the list of compounds to be tested by the outside researchers at Duke as well as by researchers at the Food and Drug Administration. Eighteen compounds were sent to Duke and the FDA.

Despite BW's favorable results against the mouse screens, the testing of AZT at Duke and the FDA during December 1984 and January 1985 did not yield positive results in human cell lines infected with HIV.

Some results were equivocal as to whether AZT was active against HIV replication, others showed no such activity, and still others indicated that AZT was toxic to human cells.

BW prepared draft, boilerplate United Kingdom patent applications for a number of the eighteen compounds, assigning AZT the lowest priority level among all BW's then-projected filings. BW traditionally files patent applications first in its home country, the United Kingdom. Unlike the United States, which gives priority to the first person to *invent*, the United Kingdom gives priority to the first person to *file* a patent application. *See* 3 DONALD S. CHISUM, PATENTS § 10.01 (1994) (CHISUM). For this reason there is an extraordinary premium on filing quickly in the United Kingdom and hence on preparing a U.K. application whenever there is the slightest suggestion that a patentable item or process might conceivably be on the horizon, even if the evidence is grossly insufficient to constitute conception.

BW did not file the AZT patent application at that time, even in the United Kingdom. BW did not take such additional steps as instituting clinical trials of AZT. Barr was denied the opportunity to prove at trial that despite the routine preparation of draft United Kingdom patent applications for AZT and other compounds around the beginning of February 1985, the BW Inventors had no reason to believe (and evinced no belief) at that time that AZT would be effective against HIV or AIDS.

On February 4, 1985 BW, which previously had sent Dr. Broder five compounds for testing against HIV in the ATH8 cell line, sent him AZT identified as Compound S. App. A, 4a. Doctors Broder and Mitsuya tested the BW compounds, using tests that BW itself had neither the expertise nor the facilities to perform. Broder and Mitsuya found AZT activity against the live AIDS virus at various concentrations, thus becoming the first to discover that AZT is active against the live AIDS virus.

On February 20, 1985 Broder informed one of the BW Inventors that the NIH experiments had shown that AZT is active against HIV. In the words of one of the BW Inventors, "[t]hings really began to move incredibly fast" once Dr. Broder's news reached BW. In the words of a BW internal newsletter, "[t]he green light was on."

BW did not overlook the enormous financial potential of AZT, either. An internal BW memo, dated April 15, 1985, noted that "[m]arket penetration would be complete with little promotional effort because of the usually fatal nature of the illness" and that "[a] *premium price* could be obtained * * * [I]f one assumes a moderate *premium* price of $10 a day for 1 year for only 10% of all infected patients, sales would be nearly $150 million for that year" (emphasis added). BW filed its patent application in the United Kingdom on March 16, 1985. App. A, 5a.

Thereafter, during clinical trials of AZT, Dr. Broder and another NIH researcher, Dr. Robert Yarchoan, conducted a patient study showing that treatment with AZT could increase a patient's T-cell count. Dr. Broder reported this to one of the BW Inventors in late July 1985. App. A, 5a.

BW (as assignee of the BW Inventors) filed its initial United States patent application on September 17, 1985. App. A, 2a. All the AZT Patents ultimately flowed from that application. Neither that application nor any other submission made to the U.S. Patent and Trademark Office named as coinventor (or even mentioned) Dr. Broder, Dr. Mitsuya, or Dr. Yarchoan. The AZT Patents were issued to BW at various times between October 1987 and June 1989. App. A, 2a n.2.

In March 1991 Barr filed an abbreviated new drug application (ANDA)[3] with the FDA seeking approval

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[3] Generic drugs must be shown to contain the same active ingredients as brand drugs and to be "bioequivalent" to such drugs. 21 U.S.C. § 355(j)(2)(A). Because the safety and efficacy of the

to manufacture and sell a generic version of AZT. This filing constituted a technical infringement of the AZT Patents. 35 U.S.C. § 271(e)(2)(A). As required by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(B), Barr notified BW of Barr's submission of the ANDA. On May 14, 1991 BW filed this patent infringement suit against Barr in the U.S. District Court for the Eastern District of North Carolina.

NIH believed that Dr. Broder and his colleagues should have been named as coinventors of the AZT Patents. On July 11, 1991 NIH granted Barr a nonexclusive license to sell AZT and authorized Barr to litigate the government's inventorship dispute with BW. Barr agreed to pay the government a royalty on all commercial sales of AZT. Barr stated publicly that the sales price of Barr's version of AZT would be substantially lower than that being charged by BW.

Among Barr's counterclaims was one for correction of the AZT Patents to list Dr. Broder and his colleagues as joint inventors. 35 U.S.C. § 256. Barr's position was and is that the coinvention of the AZT Patents by federal employees made the federal government an owner of the AZT Patents and that by virtue of the NIH license to Barr, Barr's manufacture and sale of AZT would not infringe those patents.[4]

BW denied that Doctors Broder, Mitsuya, and Yarchoan were coinventors of any of the AZT Patents. BW

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drug previously has been demonstrated in connection with the brand manufacturer's new drug application (NDA), 21 U.S.C. § 355(b)(1)(A), it need not be shown again for the generic version.

[4] Novopharm Ltd., which is not affiliated with Barr, later filed its own ANDA for AZT. BW's suit against Novopharm Ltd. and its U.S. affiliate, Novopharm, Inc. (collectively, Novopharm), for patent infringement was joined with the BW-Barr action. Novopharm, which does not hold a license from NIH, takes the position that BW's failure to list the NIH scientists as coinventors (1) renders the patents invalid and (2) constituted inequitable conduct that makes the patents unenforceable.

also contended that the doctrines of laches, estoppel, and waiver barred the assertion by these individuals—or the federal government—of any rights in the AZT Patents.

At trial Barr sought to demonstrate that (1) the activity or inactivity of AZT against the mouse retroviruses was not predictive of activity against HIV, (2) the BW Inventors were well aware of this infirmity of the BW mouse screens, and (3) the results of the testing at Duke and the FDA had been disappointing at best. This would permit the jury to find that in early February 1985, when BW prepared the draft U.K. patent application and sent AZT to NIH for testing against live HIV, the BW Inventors had no reason to believe or expect that AZT would be active against HIV. Barr wanted jury instructions that in the highly experimental and uncertain scientific area involved in the development of drugs, conception does not occur until and unless an inventor has a reasonable expectation that the invention will work in practice, and that if the jury found that the BW scientists did not have such an expectation when BW sent AZT to NIH for testing, the NIH scientists should be listed as coinventors. The district court, however, had rejected the "reasonable expectation" and the "simultaneous conception and reduction to practice" approaches before jury instructions were submitted. *See* App. B, 30a; *Burroughs Wellcome Co. v. Barr Laboratories, Inc.*, 828 F. Supp. 1200, 1205 (E.D.N.C. 1993) (denying summary judgment motions).

"Conception" (for purposes of making one an inventor) has two elements. The first element is a definite and permanent idea of the complete and operative invention as it is to be applied in practice. App. B, 30a. The second is the definition and preservation of the inventor's idea in a manner (typically written) that enables one of ordinary skill in the art to reduce the invention to practice. App. B, 30a-31a. The district court correctly recognized that the focus of the dispute between Barr/NIH and BW is on the first element. App. B, 31a.

The district court ruled, however, that "so long as the [inventor's] idea is sufficiently defined and preserved, the law does not require that the inventor's idea be reasonable, scientifically accurate, or capable of being proved." App. B, 30a. Accordingly, the district court refused to let Barr demonstrate that the BW Inventors did not have a reasonable belief that AZT would work against the HIV virus before the BW Inventors heard the results of the tests conducted by Dr. Broder and Dr. Mitsuya. Having reached this conclusion, the district court granted BW's motion for judgment as a matter of law, FED. R. CIV. P. 50(a), stating that the BW Inventors had conceived of the subject matter of the inventions embodied in all six of the AZT Patents at some time *before* AZT was sent to Dr. Broder on February 6, 1985. App. B, 32a-33a.[5]

Barr appealed to the Court of Appeals for the Federal Circuit. 28 U.S.C. § 1295(a)(1). There Barr pointed out that the standard applied by the district court requires nothing more for conception than someone's thinking that somewhere in a warehouse full of identified compounds is one that may turn out to be effective against one of dozens of identified diseases. At least in the unpredictable

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[5] The district court also denied Barr's motion for partial summary judgment on the issue of whether estoppel, laches, or waiver could be invoked against a property right claimed by the United States. App. B, 34a-36a. The court found "no basis for finding [sufficient to grant a motion for summary judgment] that the government has a constitutionally-protected property interest in the [AZT Patents]" but went on to say that "[w]hether these equitable doctrines can be applied in this case is a question that cannot be decided as a matter of law. This ruling in no way expresses any opinion as to whether the elements of these doctrines can be satisfied in this case based upon the evidence." App. B, 36a. Barr raised this issue before the court of appeals, which mentioned the issue in passing, App. A, 5a-6a, but did not further address it. Accordingly, Barr has not raised the issue in this petition, *see* ROBERT L. STERN, EUGENE GRESSMAN, STEPHEN M. SHAPIRO & KENNETH S. GELLER, SUPREME COURT PRACTICE 342-43 (7th ed. 1993) (STERN & GRESSMAN), but expects to renew the issue below when appropriate.

area of treatment of the human body, Barr stated, "the standard would reward the generation of a lengthy candidate compounds list and would deny inventorship to those who make the crucial and often inventive contribution necessary to narrow the field of candidate compounds to a list of actually useful compounds."

The court of appeals affirmed the legal conclusion of the district court, remanding one of the AZT Patents to the district court but sustaining the finding of BW ownership of the other five. App. A, 13a-19a. The court said that the "definite and permanent idea" required for conception meets that standard "when the inventor has a specific, settled, idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue," App. A, 9a, but that "[a]n inventor's belief that his invention will work [is] irrelevant to conception." App. A, 10a. Apparently agreeing with the district court, the court continued that this is so even "when the invention deals with uncertain or experimental disciplines, where the inventor cannot reasonably believe an idea will be operable until some result supports that conclusion." App. A, 9a-10a.

Based upon the foregoing statement of what it viewed as the law, the court of appeals rejected the idea that an inventor in an uncertain field must have some basis for believing that his "invention" will work. App. A, 9a-11a. Confusingly, the court then said that "[a] conception is not complete if the subsequent course of experimentation, especially experimental failures, reveals uncertainty that so undermines the specificity of the inventor's idea that it is not yet a definite and permanent reflection of the complete invention as it will be used in practice." App. A, 11a-12a. Thus the court said, almost in the same breath, that conception is *completed* before there is any notion as to whether an invention will work *and* that if subsequent experimentation undermines the idea, conception has *not* occurred. These two statements are inconsistent and leave

the scientific community without a clear standard as to what constitutes conception in the fields of chemistry and biology.

The court of appeals affirmed the district court's decision as to five of the six AZT Patents, stating that "[w]hether or not Burroughs Wellcome believed the inventions would in fact work based on the mouse screens is irrelevant." App. A, 16a. As to the remaining patent, the court said that the record was inconclusive on whether conception of the increase-of-T-cell-count idea had occurred before the clinical trials were conducted at NIH by Doctors Broder and Yarchoan. App. A, 16a-19a. Accordingly, the decision as to that patent was vacated and remanded for further proceedings. App. A, 19a.[6]

Circuit Judge Lourie filed a separate opinion, stating that the majority's opinion confused the ideas of conception, corroboration, and reduction to practice. App. A, 20a. He agreed with the decision on five of the patents but disagreed with the remand of the sixth, stating that its method "is an inherent, inevitable result of the practice of the other [AZT Patents]" and hence cannot be separated from them. App. A, 21a.

Novopharm sought rehearing on the ground that the experimental failures at Duke and the FDA came within

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[6] This remand for further factual development regarding one of the six patents technically deprives the judgment below of finality. That fact should not preclude review now by this Court. First, finality is a prudential matter rather than a jurisdictional requirement where the judgment to be reviewed is that of a federal court. *Compare* 28 U.S.C. § 1254(1) (authorizing Supreme Court review of "[c]ases in the courts of appeals . . . before or after rendition of judgment or decree") *with* 28 U.S.C. § 1257 (limiting Supreme Court review of state court decisions to "[f]inal" judgments). Further, the decision below *is* final as to the only issue likely to command the attention of this Court—whether one can conceive of an invention for patent purposes when one has no idea whether the invention will work. *See, e.g., Larson v. Domestic & Foreign Corp.*, 337 U.S. 682, 685 n.3 (1949); *United States v. General Motors Corp.*, 323 U.S. 373, 377 (1945).

the court of appeals' statement that conception may be incomplete if subsequent experimental failures occur. Accordingly, Novopharm stated, the district court's grant of judgment as a matter of law in favor of BW was incorrect and reversal of the decision below was in order. Rehearing was denied, without opinion, on December 15, 1994.

REASON FOR GRANTING THE WRIT

THE COURT OF APPEALS' VIEW OF CONCEPTION PERMITS MERE SPECULATION OR HOPE TO SUBSTITUTE FOR THE REASONABLE EXPECTATION REQUIRED BY THE PATENT LAW.

A. The History of the Patent Law, Including the Decisions of This Court, Counsels Against the Unduly Free Granting of Patent Monopolies.

Our patent law flows from the Constitution: Congress is authorized "To promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries." U.S. CONST. art. I, § 8, cl. 8. While the Patent Clause appears among the Constitution's grants of power to the Congress, its limitations reflect the Framers' hostility to unearned monopolies. *Graham v. John Deere Co.*, 383 U.S. 1, 5-10 (1966). Thomas Jefferson, the author of the 1793 Patent Act [7] and a renowned inventor, "had an instinctive aversion to monopolies." *Id.* at 7. Though he eventually came to accept the idea of limited patent monopolies, he did so not because he believed inventors should have exclusive rights to their inventions but because "[t]he patent monopoly . . . was a reward, an inducement, to bring forth new knowledge. The grant of an exclusive right to an invention was the creation of society—at odds with the inherent free nature of disclosed ideas—and was not to be freely given." *Id.* at 9. "The Framers plainly did not want [patent] monopolies freely granted." *Great Atlantic*

[7] The concepts underlying the 1793 statute remain fundamental features of our patent law today. 1 CHISUM, at OV-3.

& Pacific Tea Co. v. Supermarket Equipment Corp., 340 U.S. 147, 154 (1950) (Douglas, J., concurring).

Only one month after deciding *Graham*, this Court offered an illuminating example of the *limited* nature of the patent monopoly. Addressing the patentability of a chemical process, the Court wrote that the requirement that an invention be "useful" to be patentable, 35 U.S.C. § 101, does not mean merely that the process be non-detrimental or worthy of study. *Brenner v. Manson*, 383 U.S. 519 (1966). Instead, the patent statute is to be read narrowly, to authorize the issuance of a patent and the creation of a monopoly "only if clearly commanded" by its text. *Id.* at 534.

> Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a *vast, unknown, and perhaps unknowable area.* Such a patent may confer a power to block off *whole areas of scientific development,* without compensating benefit to the public.

Id. (emphasis added). The Court concluded by noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." *Id.* at 536.

B. The Court of Appeals' Decision Will Increase Patent Monopolies in a Manner Inconsistent With the Patent Law.

"The attempts through the years to get a broader, looser conception of patents than the Constitution contemplates have been persistent." *Great Atlantic & Pacific*, 340 U.S. at 156 (Douglas, J., concurring). Regrettably, the court of appeals has yielded in the instant case to the temptation described by Justice Douglas.

The court of appeals' has departed from existing law in a way that tips the scales significantly in favor of the

brand pharmaceutical industry, with its monopoly prices, and against the generic drug industry, which operates in the free market. The difference can be significant:

> [F]or poorer people—the users for whom access to generic drugs is most important—a pecuniary saving on drugs may have important health benefits. The difference between sinking, say, 3% and 20% of one's income into pharmaceuticals spells a large difference in the range of economically accessible food and shelter.

In re Barr Laboratories, Inc., 930 F.2d 72, 75, 289 U.S. App. D.C. 187, 190 (D.C. Cir.), *cert. denied*, 502 U.S. 906 (1991).

The decision below also is likely to affect the important role of NIH in developing new pharmaceutical products. If NIH continues its past practice of cooperation with the private sector, the court of appeals' bias in favor of finding conception at the earliest possible time will mean that taxpayers' funds will go to provide private drug manufacturers with monopoly pricing opportunities. If, on the other hand, NIH decides to cease participating in an exercise that enriches private manufacturers at the expense of the public treasury, efforts to find new drugs likely will be hampered significantly.

The cases discussed above reflect this Court's recognition that the presumption of our patent code is against the grant of patent monopolies. The case at bar is analogous and the same principle should be applied here. This time the defect of the decision below is not in permitting patenting in the absence of utility, which this Court barred in *Manson*, or in the absence of novelty, which this Court barred in *Great Atlantic & Pacific* and other cases. Here the error is in the invitation to become an inventor by claiming that any number of identified compounds will cure any number of identified diseases. No matter how many compounds or diseases are named, and no matter how little faith the namer has that *any* of the

named compounds will cure *any* of the named diseases, the namer will be the inventor of a patentable process if *any* of the compounds turns out to cure *any* of the diseases. That is the import of the decision below.

Where a patent has joint inventors, each (or his assignee) is the owner of the patent and may practice the patent without the permission of his coinventors. 35 U.S.C. §§ 261-262. Thus an approach that minimizes the number of joint inventors will contribute to patent monopolization. The facts of this case are instructive. Consistent with the marketing memorandum discussed above, BW initially made the most of its monopoly by charging as much as $10,000 per year per patient for AZT. This amount later was reduced under intense public pressure. By contrast, NIH, which often performs the role it did in this case, has granted a *non*exclusive license to Barr. Barr in turn has promised to sell AZT for considerably less than BW. Further, should the joint inventorship of the NIH scientists be recognized, NIH will retain the right to license drug companies in addition to Barr to produce AZT.

Conception requires more than a mere hope or expectation, *Alpert v. Slatin*, 305 F.2d 891, 894 (C.C.P.A. 1962), and more than "mere speculation or . . . probable deduction from facts already known," *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1207, 18 U.S.P.Q.2d 1016, 1021 (Fed. Cir. 1989) (interior quotation marks omitted), *cert. denied, sub nom. Genetics Inst., Inc. v. Amgen, Inc.*, 502 U.S. 856 (1991). It must be "based on something ascertained, something definite and certain." *Bourne v. Jones*, 114 F. Supp. 413, 418, 98 U.S.P.Q. 206, 209 (D. Fla. 1951), *aff'd*, 207 F.2d 173 (5th Cir.), *cert. denied*, 346 U.S. 897 (1953).

In most patent cases the reasonable expectation of the inventor is not at issue. Most cases do not arise in highly experimental or uncertain areas. Typically there is existing knowledge that itself provides a reasonable expecta-

tion that a new idea will work. Where the invention arises in an area about which little is known, though, the reasonable expectations of the inventor are properly an issue. The predecessor of the Court of Appeals for the Federal Circuit recognized this thirty years ago, stating that where the invention is "a method of treating the human body . . ., conception thereof is a far different thing than merely thinking of the use of the compound. There must be some concomitant reasonable understanding or appreciation of the fact that the compound would work and in what way." *Biel v. Chessin*, 347 F.2d 898, 902-03, 146 U.S.P.Q. 293, 296-97 (C.C.P.A. 1965) (Rich, J.). So the law used to be, but the decision in the case at bar brushed off the *Biel* standard as dictum.

The court of appeals all but ignored the line of cases relating to simultaneous conception and reduction to practice. This doctrine is applied to situations "where results at each step do not follow as anticipated, but are achieved empirically by what amounts to trial and error." *Alpert*, 305 F.2d at 894, 134 U.S.P.Q. at 299; *see Smith v. Bosquet*, 111 F.2d 157, 45 U.S.P.Q. 347 (C.C.P.A. 1940). For this reason, there in effect *cannot* be conception until the invention has been shown to work. The experimental failures of AZT in the Duke and FDA trials exemplify the circumstances in which this doctrine applies, but the court of appeals brushed off this idea as well. App. A, 11a-12a.

By way of example, a drug company uninvolved in this case recently advertised that it had tested 3000 compounds before discovering one that worked against life-threatening infections, and that thereafter it tested 27,000 more "to ensure that [it] had the best one." App. C, 38a.[8] Under the decision below, the company reached the point of conception as to at least 3000, and arguably as many as 30,000, compounds at the moment the compounds initially were selected for testing. Such is not the law.

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[8] The advertisement is not part of the record.

To summarize, the court of appeals has said in this case that even in the uncertain field of human biology and chemistry, a researcher who has no expectation or belief that his idea will work nevertheless is the inventor. The same court, which hears all appeals in patent cases, previously has indicated that there is no limit on the number of compounds that one can contend will act against a disease. *MacMillan v. Moffett*, 432 F.2d 1237, 167 U.S.P.Q. 550 (C.C.P.A. 1970). The invitation to abuse is unmistakable. Like the broad, open-ended approach to the requirement of utility that this Court rejected in *Manson*, the approach of the court of appeals to conception here "may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer a power to block off whole areas of scientific development, without compensating benefit to the public." *Manson*, 383 U.S. at 534.

More than a century ago this Court warned unanimously against "the indiscriminate creation of exclusive [patent] privileges" as a course that tends to obstruct rather than stimulate invention. *Atlantic Works v. Brady*, 107 U.S. 192, 200 (1882); *accord Cuno Eng'g Corp. v. Automatic Devices Corp.*, 314 U.S. 84, 92, 51 U.S.P.Q. 272, 276 (1941). "It was never the object of [the patent] laws," wrote Justice Bradley, "to grant a monopoly for . . . every shadow of a shade of an idea." *Brady*, 107 U.S. at 200.

In *Brady*, and later in *Cuno* and *Great Atlantic & Pacific*, this Court demanded substantial novelty as a prerequisite for a patent. In *Manson* this Court demanded practical utility as a prerequisite for a patent. Today this Court faces the choice between a loose and a rigorous standard of conception. The loose standard, adopted by the court of appeals, permits a researcher to "conceive" a method of treatment simply by declaring that somewhere in a potentially limitless list of compounds is one that will counteract one of a potentially limitless

list of diseases. The rigorous standard, which this Court should adopt, requires at least a reasonable belief or expectation that the proposed method will work in practice. This Court should grant the writ and then recognize the rigorous standard as correct.

CONCLUSION

If not reviewed by this Court, the court of appeals' view of what constitutes conception in an uncertain or experimental field of scientific endeavor will permit mere speculation or hope to substitute for the more concrete level of certainty required by the patent law. This allows conception based upon research plans rather than upon true inventions—a result that is inconsistent with the patent law as well as with common sense. The result below will enhance monopoly drug pricing and either discourage the NIH from cooperating with the private sector in developing new drugs or result in the expenditure of tax money to benefit monopolists. A writ of certiorari should issue to review the judgment of the Court of Appeals for the Federal Circuit.

Respectfully submitted,

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